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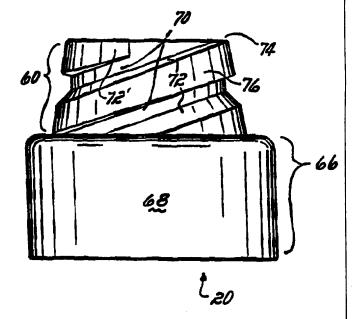
#### **Published**

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(54) Title: PLASTIC NEEDLELESS VALVE HOUSING FOR STANDARD MALE LUER LOCKS

#### (57) Abstract

A needleless site (10) includes a slit septum valve (12) held in a plastic housing (20) having a thin-walled cylinder (70) sized to fit inside the lock nut (64) of an ISO male luer lock (54) and a wedging member such as tapered threads (72) to strengthen the cylinder (70) and wedge within lock nut (64) to securely lock male luer lock (54) to site (10). The valve (12) of site (10) is tubular and includes a flange (44) gripped between housing portions (18, 20) having an annular ring (45) digging into the flange.



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- 1 -

# PLASTIC NEEDLELESS VALVE HOUSING FOR STANDARD MALE LUER LOCKS

#### Related Application

This application is a continuation-in-part of co-pending application Serial No. 08/160,047, filed November 30, 1993, and assigned to the assignee hereof. The disclosure of aforesaid pending application Serial No. 08/160,047 is incorporated herein by reference.

#### **Background of the Invention**

#### I. Field of the Invention

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The present invention relates to medical valves through which fluid may be injected into or withdrawn from a patient without requiring use of sharp needles, and more specifically, to such valves in plastic housings sized to mate with a standard ISO or ANSI male luer lock.

#### II. Description of Prior Art

In many medical situations, it is typical to provide a valve, such as a solid rubber septum on a Y-site or a sample site, which is

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-2-

accessible by a needle piercing through the septum in order to introduce fluids into, or remove blood from, a line coupled to a patient's circulatory system via a catheter inserted into the patient such as through the arm. With such needle-piercable valves, the top of the valve is usually adjacent to or at the top of the valve or site housing and so may be readily wiped clean before each use. While this is advantageous for aseptic purposes, the use of sharp needles presents hazards to medical and other personnel due to the risk of needle sticks which could transmit disease.

In order to reduce or eliminate needle stick problems, it has been proposed to replace the needle-piercable rubber septum with a blunt cannula-accessible valve, such as a rubber piece with a slit septum. The slit septum opens under pressure of a blunt cannula thereagainst to allow the blunt cannula to pass into and through the slit and into communication with the fluid line. The most commonly employed blunt cannulas in the medical field are male luer tapers (an example of which is the distal plastic end of a typical syringe). Many male luer tapers are part of a luer lock and thus also have an internally threaded nut or collar associated therewith to securely lock to a female luer cylinder with lock tabs thereon. The dimensions of the locking nut of standard luer locks conform generally to ISO standards thus dictating the size requirements that must be met to mate with a male luer lock. These size requirements have presented difficulty in providing a needleless valve in a plastic housing.

As will be appreciated, it is most desirable to situate the slit septum valve at the top of the valve housing for aseptic purposes. But this

requirement has presented an obstacle to housing the valve in such a manner that a male luer lock is usable with that valve. Desirably, plastics are used in the medical field. So it would be advantageous if the valve housing could be entirely of plastic. But, the plastic housing must be thick enough to withstand the various forces it will encounter in use. Unfortunately, the rubber valve piece itself requires so much bulk that difficulties have been encountered in providing a plastic housing about the valve that is sturdy and safe, but yet small enough to fit within the nut of the luer lock to be secured thereto. The requirements on the plastic housing, coupled with the minimum size requirements of the slit valve piece, have thus dictated that the overall size of the plastic housing be larger than the internal diameter of the locking nut of a standard ISO or ANSI male luer lock. With such devices, therefore, it has been necessary to use an adaptor having a blunt needle and lock nut sized to fit the valve housing at one end and a standard female luer cylinder with lock tabs at the other end. The adaptor introduces increased costs, and imposes risk of misuse and error in the field.

Another approach would be to provide split luer wings above the top of the valve so that the valve may still be cleaned, yet the male luer lock nut may be securely locked to the valve housing as shown in U.S. Patent No. 5,203,775, the disclosure of which is incorporated herein by reference. It is desirable, however, to have the locking interaction of the nut and the valve housing occur along the side of the housing at or below the top level of the valve itself. As mentioned above, however, this has

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not been found to be readily achievable where the valve housing is made of plastic.

One proposal that does shrink the size of the housing so that the housing may fit within the nut to be locked about the sidewall of the valve housing is to use a thin-walled piece of metal, such as a stamped piece of aluminum with lugs projecting from the side thereof, for the housing. However, the rest of the valve housing, especially the portions that mate to the fluid line, will normally be of plastic making the aluminum/plastic valve housing less desirable from a manufacturing standpoint. Also, medical users tend to prefer plastic for a variety of reasons making the metal/plastic valve housing undesirable from a user standpoint as well.

#### **Summary of the Invention**

The present invention provides a blunt cannula-accessible valve, such as a slit septum valve, situated in and at the top of a plastic housing which is sized to lockingly engage a male luer lock nut with the luer taper inserted against or into the valve. To this end, and in accordance with the present invention, the valve is contained within a thin-walled plastic housing or cylinder with the top of the valve at the top opening of the cylinder. The cylinder is sized to fit within the luer lock between the lock nut and the taper with the taper inserted through the valve. Associated with the thin-wall cylinder is a tapered wedging member that is narrow at the top of the cylinder adjacent the top of the valve so that at least the upper edge thereof fits completely within the male luer lock nut

between the nut and the luer taper. The tapered wedging member traverses down the sidewall of the cylinder below the top of the valve, and tapers outwardly to increase in diameter as it progresses down the cylinder. The wedging member thus provides strength to the otherwise thin plastic housing wall while at the same time forming a wedge against the internal threads of a male luer lock nut. Consequently, as the male luer taper is inserted into the valve, the luer lock is secured to the valve. The tapered wedging member may be provided by a tapered thread structure, such as a pair of intertwined threads, spirally formed about the thin-wall housing.

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By virtue of the foregoing, there is thus provided a needleless valve plastic housing that is sturdy and reliable, yet mates and locks directly to a standard ISO or ANSI male luer lock with the taper thereof inside the valve through the top of the valve at the top of the housing. These and other objects and advantages of the present invention shall be made apparent from the accompanying drawings and description thereof.

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#### Brief Description of the Drawings

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention and, together with a general description of the invention given above, and the detailed description given below, serve to explain the principles of the invention.

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Fig. 1 is a cross-sectional view of a medical site including a needleless valve in a plastic housing incorporating a tapered thread wedging member in accordance with the principles of the present invention;

Fig. 2 is a side view of the tapered thread housing of Fig. 1;

Fig. 3 is a top view of the site of Fig. 1;

Fig. 4 is a cross-sectional view of the site of Fig. 1 with a standard ISO or ANSI male luer lock attached thereto for purposes of explaining the principles of the present invention; and

Fig. 5 is a cross-sectional view of another medical site including the tapered thread housing of Fig. 1.

#### **Detailed Description of the Drawings**

With reference to Fig. 1, there is shown in cross-section an embodiment of a medical site 10 incorporating the features of the present invention. Site 10 in the embodiment shown here includes a slit septum elastomeric (e.g., silicon or polyisoprene rubber) valve 12 and a disc valve 14 held within plastic (e.g. polycarbonate, Dow Isoplast, rigid PVC, or Ektar) housing 16. Plastic housing 16 includes three portions, namely, male luer lock fluid connector 17, actuator housing 18 and tapered thread housing 20, all bonded together such as with solvent, UV cured adhesive or ultrasonic welding, or they may be frictionally or snap fit together.

Connector 17 is a fluid port and includes a standard ISO or ANSI luer taper 22 and locking collar 24 for fluid connection to a fluid line (not shown) coupled, for example, to a patient. Actuator housing 18 contains disk valve 14 comprised of actuator 26 and resilient disc 28, the underside

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-7-

skirt 30 of which is seated on nipple 32 of housing 17 projecting into housing 18. Disc 28 normally bears against valve seat 34 of housing 18 to stay closed but opens under pressure such as from actuator 26 pushed thereagainst. Actuator 26 is open through its interior 36 to permit fluid to flow therethrough and over disc 28 when disc valve 14 is opened. Fluid may then pass out of the lower or outlet end of housing 18 such as via connector 17.

Focusing now on valve 12 and its associate housing 20, valve 12 has a tubular or cylindrical body 40 defining a fluid path 41 therein. Body 40 has an inner diameter of about .195 inch and an outer diameter of about .246 inch. Extending outwardly about .042 inch from the bottom edge 42 of body 40 is an annular lip or flange 44. Actuator housing 18 acts as a support member on which flange 44 sets. Valve housing 20 and actuator housing 18 cooperate to grip valve 12 with flange 44 therebetween. An annular ring 45 is interposed between housing 20 and flange 44. Annular ring 45 may be formed as part of housing 20 and depend therefrom to dig into flange 44 adjacent edge 42 to deform same as seen in Fig. 1. Ring 45 securely holds valve 12 to housing 16 and prevents valve 12 from being extruded inwardly. Ring 45 could, alternatively, be formed on housing 18.

The top edge 46 of body 40 is integrally joined to a closing web 48 to provide an environmental barrier to fluid path 41. To facilitate use of valve 12, a .150 inch slit 50 is formed through web 48 to receive a blunt cannula such as male taper 52 of a male luer lock 54, for example

(see Fig. 4), into valve 12 through slit 50. Web 48 has a generally flat top 56 and a convex underside 58 and may include structure such as one or more ribs or steps (not shown) to assist in keeping slit 50 in a closed and sealed state until taper 52 bears thereagainst. Extending from underside 58 and along slit 50 may be duckbill lips 59.

upper portion 60 (see Fig. 2) designed to hold tubular body 40 of valve 12

Housing 20 is a single injection molded piece and has an

and to mate with the interior threads 62 of locking nut 64 of male luer lock 54. Housing 20 also includes a lower portion 66 designed to matingly fit over actuator housing 18 to be secured thereto. Lower portion 66 may also be knurled (not shown) about its exterior surface 68 to facilitate handling of site 10 by a user (not shown). Upper portion 60 of housing 20 is sized thin enough to fit into nut 64, yet robust enough to secure to luer lock 54 while protecting valve 12 in normal use. To this end, in accordance with the principles of the present invention, the upper portion 60 of housing 20 may be considered as having two aspects, one being a thin-walled housing cylinder 70 and the other being a wedging member such as a pair of tapered threads 72. Thin-wall cylinder 70 is defined as the cylindrical aspect of housing 20 adjacent and coaxial with tubular body portion 40 of valve 12 and is about .012 inch thick. Cylinder 70 has an inner diameter of about .246 inch to match to the outer diameter of valve body 40, and an outer diameter of about .270 inch. With the thin-wall, it will be

appreciated that cylinder 70 is sized to be received into the interior of

locking nut 64 of luer lock 54, which has a minimum inner diameter of

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about 7 mm (.27 inch). However, cylinder 70 is not itself thick enough to guard valve 12 or withstand even normal use, nor does cylinder 70 itself lock to luer lock 54. The provision of a tapered wedge member such as one or more threads 72 solves these problems.

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With further reference to Figs. 2 and 3, it may be seen that tapered threads 72 are formed about and spiral downwardly from top end 74 of cylinder 70. The start points 72' of the threads 72 are on opposite sides of cylinder 70 so that threads 72 intertwine as seen in Fig. 3. Cylinder 70 defines the minor diameter of threads 72 and the distal or outer edge 76 of each thread 72 defines the major diameter thereof. The major diameter 76 extends radially outwardly of cylinder 70 only slightly (about .008 inch) at top end 74 and is thus narrow at the top end 74 of cylinder 70, to be sized to still be received within the interior of locking nut 64. As threads 72 progress spirally downwardly towards lower portion 66, the major diameter 76 increases in thickness to about .036 inch such that the outer diameter thereof is larger than the inner diameter of lock nut 64. Thus, at the lower end of threads 72 spaced from top end 74, the threads are wider than at top end 74. Threads 72 are 10 pitch with double start and cylinder 70 is about .171 inch long or tall to be coextensive with tubular body 40 of valve 12 such that the top 56 of slit web 48 is at or generally flush with opening 70 at top end 74 of housing 20 (and cylinder 70) to be aseptically cleaned by wiping thereacross. Top end 74 of housing 12 defines a lip projecting inwardly from cylinder 70 about .023 inch to overlie top edge 46 of valve 12 and help hold valve 12 in place with the

top surface 56 thereof generally flush with housing top end 74. Top surface 56 is thus accessible via inlet opening 78 of cylinder 70 to be cleaned with a gauze pad (not shown), for example, wiped thereacross.

It will be appreciated that the tapered threads 72 are integral with cylinder 70 and function to strengthen cylinder 70 without making housing 20 too large to mate with lock nut 64, yet provide a positive and gradual locking function between site 10 and luer lock 54. These functions are thus provided in a plastic housing for a needleless valve which is surfaced at the top of the valve housing for aseptic purposes, but which is lockingly receivable into a standard ISO or ANSI male luer lock.

In use, flat top 56 of web 48 is wiped clean and, as seen in Fig. 4, taper 52 of luer lock 54 (luer lock 54 could be part of a syringe 80 as is well known) is inserted into and through slit 50 of web 48. As that occurs, the top end 74 of upper portion 60 of housing 20 is received into the interior of locking nut 64. Nut 64 is rotated as it passes over top end 74. Threads 62 of luer lock 54 and tapered thread 72 of housing 20 cooperate to draw taper 52 into actuator housing 18. Taper 52 then passes into fluid path 41 and impacts against actuator 26 moving it downwardly into disc 28 to thereby open same for fluid to flow through taper 52 and actuator 26, over disc 28 and through luer taper 22 of connector 17 along the path of Arrows A (or vice versa) to complete a fluid connection through site 10. Also, the portions of web 48 to either side of slit 50 flex downwardly and outwardly to either side of taper 52 like lips, as at 90 in Fig. 4. At the same time, lock nut 64 does not merely threadably engage

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PCT/US94/13757 WO 95/15195 -11-

> to housing 20 as would be typically expected, but instead is wedged thereagainst by coaction of the material of plastic housing upper portion 60, and particularly tapered threads 72, and the major diameter 92 of locking collar 64 to thereby securely hold male luer lock 54 to site 10. Luer lock 54 may be easily removed by reverse rotation of locking collar 64 to thereby release the wedge and remove taper 54 which also recloses disc valve 14 and slit septum valve 12.

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With reference to Fig. 5, another site 10' is shown including the tapered thread housing 20 as in the case of site 10 of Fig. 1. To this end, site 10' of Fig. 5 includes valve 12 and thread housing 20 as abovedescribed. However, connector 17 and actuator housing 18 are combined into one housing piece 18' to support spring-biased disc valve 14'. Disc valve 14' includes a plastic disc 28' which is biased closed by spring 29' against valve seat 34' defined at the lower edge 42 of valve 12. Spring 29' seats over mouth 32' of housing 18' and within a groove 30' defined under disc 28'. Extending up from disc 28' is actuator piece 26' to cooperate with taper 52 passed through valve 12 to push disc 28' away from valve seat 34' to permit fluid communication through housing 16' similar to that in the case of site 10 of Fig. 1.

While the present invention has been illustrated by the description of an embodiment thereof, and while the embodiment has been described in considerable detail, it is not intended to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art.

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For example, the secondary or check valve of the site of aforementioned parent application Serial No. 08/160,047 could be disc valve 14 as described herein. Additionally, the fluid port of connector 17 could instead be provided by a Y-site or T-shaped sample or injection site, or a tubing port, as will be readily appreciated. Additionally, instead of the major diameter 76 of the wedging member tapering outwardly, that outer surface could be held at a fixed diameter with the minor diameter of threads 72 tapering outwardly instead. Or both the minor and major diameters of thread(s) 72 could taper outwardly. Further, the thread tapering could be in discrete portions of the overall thread length or the threads may be truncated and traverse only partway down cylinder 70. In any event, the top end must fit completely within the locking collar and the lower end must be sized to wedge against the internal threads (major and/or minor diameters) of the locking collar. Moreover, although the wedging member is described as a thread structure or pair of threads, a single thread or other tapered wedging member structure may be employed to functionally thicken or strengthen cylinder 70 and also lock within luer lock 54. Alternatively, where the primary concern is to strengthen the housing, the major and minor diameters could be uniform, i.e., non-tapered, such as a thread chased down a cylinder. The invention in its broader aspects is therefore not limited to the specific details, representative apparatus and method and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the scope or spirit of applicant's general inventive concept.

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- 13 -

Having described the invention, what is claimed is:

1. A medical device (10) for coupling to a standard male luer lock (54) having a luer taper (52) and an internally threaded locking nut (64) thereabout, the medical device including a normally-closed valve (12) openable under pressure of the taper (52) of the male luer lock thereagainst and being characterised by a thin-walled plastic cylinder (70) surrounding the valve (12) and having an outer diameter sized to be received into the interior of the locking nut (64) of the male luer lock, the cylinder (70) having an opening (78) with a top surface (56) of the valve being situated at the opening (78) of the cylinder (70), and a tapered wedging member (72) extending about the plastic cylinder (70) and having (i) a narrow end (74) adjacent the cylinder opening (78) sized to be received into the interior of the locking nut (64) of the male luer lock, and (ii) a wider end spaced from the cylinder opening (78) such that the wedging member (72) strengthens the cylinder (70) and interacts with the internal threads of the locking nut (64) of the male luer lock to lock the male luer lock (54) to the device with the valve (12) opened by the luer taper (52).

2. A medical device (10) for coupling to a standard male luer lock (54) having a luer taper (52) and an internally threaded locking nut (64) thereabout, the medical device including a normally-closed valve (12) openable under pressure of the taper (52) of the male luer lock (54)

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- 14 -

thereagainst and being characterised by a thin-walled plastic cylinder (70) surrounding the valve (12) and having an outer diameter sized to be received into the interior of the locking nut (64) of the male luer lock, the cylinder (70) having an opening (78) with a top surface (56) of the valve being situated at the opening (78) of the cylinder, and a thread (72) spiraling along the cylinder away from the cylinder opening (78) and sized to strengthen the cylinder (70) and interact with the internal threads of the locking nut (64) of the male luer lock (54).

3. A medical device (10) for coupling to a standard male luer lock (54) having a luer taper (52) and an internally threaded locking nut (64) thereabout, the medical device including a normally-closed slit septum (48) valve (12) openable under pressure of the taper (52) of the male luer lock (54) thereagainst and being characterised by a thin-walled plastic cylinder (70) surrounding the valve (12) and having an outer diameter sized to be received into the interior of the locking nut (64) of the male luer lock, the cylinder (70) having an opening (78) with the slit septum (48) being situated at the opening (78) of the cylinder (70), and a plastic tapered thread (72) extending about the plastic cylinder (70) and having (i) a narrow end (74) adjacent the cylinder opening (78) sized to be received into the interior of the locking nut (64) of the male luer lock, and (ii) a wider end spaced from the cylinder opening (78) such that the thread (72) strengthens the cylinder (70) and interacts with the internal threads of the locking nut (64) of the male luer lock to lock the male luer lock (54) to

- 15 -

the device with the valve (12) opened by the luer taper inserted into the slit septum (48).

- 4. A medical device as claimed in either claim 2 or 3 further characterised by a second thread (72) extending about the plastic cylinder (70) and intertwined with the first-mentioned thread (72).
- 5. A medical device as claimed in claim 4 wherein the second thread (72) is tapered with (i) a narrow end (74) adjacent the cylinder opening (78) sized to be received into the interior of the locking nut (64) of the male luer lock, and (ii) a wider end spaced from the cylinder opening (78) such that the first and second threads cooperate to strengthen the cylinder (70) and interact with the internal threads of the locking nut (64) of the male luer lock to lock the male luer lock (54) to the device with the valve (12) opened by the luer taper (52).

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6. A medical device as claimed in claim 1 further characterised by a second wedging member (72) having (i) a narrow end (74) adjacent the cylinder opening (78) sized to be received into the interior of the locking nut (64) of the male luer lock, and (ii) a wider end spaced from the cylinder opening (78) such that the wedging members (72) strengthen the cylinder (70) and interact with the internal threads of the locking nut (64) of the male luer lock to lock the male luer lock (54) to the device with the valve (12) opened by the luer taper (52).

PCT/US94/13757

- 16 -

WO 95/15195

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- 7. A medical device as claimed in any preceding claim wherein the cylinder (70) and thread or wedging member (72) are integrally formed as a single piece.
- 8. A medical device as claimed in any preceding claim wherein the valve (12) is held by a housing (20), the cylinder (70) defining a portion of the housing (20).
- 9. A medical device as claimed in claim 8 wherein the valve (12) includes an annular flange (44), and the medical device further includes a support member (18) cooperating with the housing (20) to grip the valve flange (44), the medical device further characterised by a depending annular ring (45) formed on the housing (20) and situated to engage the flange (44).
- 10. A medical device as claimed in any preceding claim wherein the wedging member or thread (72) is comprised of plastic.
- 11. A medical device as claimed in any preceding claim wherein the wedging member or thread (72) has a major diameter and a minor diameter, and being further characterised in that at least one of the major and minor diameters is tapered so as to be narrow adjacent the cylinder opening (78) and wider spaced from the cylinder opening (78).

- 17 -

12. A medical device as claimed in claim 11 wherein only the major diameter is tapered.

taper (52) including a normally-closed elastomeric valve (12) having a tubular body (40) and being openable under pressure of the taper (52) thereagainst, a plastic housing (16) surrounding the valve, and being characterised by an annular flange (44) extending outwardly of the tubular body (40), the housing having first and second portions (18,20), the flange (44) being situated between the housing first and second portions (18,20) whereby to grip the valve (12), and an annular ring (45) interposed between the flange (44) and one of the housing portions (18,20) situated to dig into the flange (44).

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- 14. A medical device as claimed in claim 13, the ring (45) being formed as part of one of the housing portions (18,20).
- 15. A medical device as claimed in either claim 13 or claim 14 wherein the first housing portion (20) surrounds the tubular body (40) of the valve (12), the ring (45) being interposed between the first housing portion (20) and the flange (44).
- 16. A medical device as claimed in claim 15 wherein the ring (45) is formed as part of the first housing portion (20).

#### AMENDED CLAIMS

[received by the International Bureau on 01 May 1995 (01.05.95); original claims 1-16 replaced by amended claims 1-18 (6 pages)]

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A medical device (10) for coupling to a standard male luer lock (54) having a luer taper (52) and an internally threaded locking nut (64) thereabout, the medical device including a normally-closed valve (12) openable under pressure of the taper (52) of the male luer lock thereagainst and a plastic housing (20) surrounding the valve (12), the housing having an opening (78) with a top surface (56) of the valve being situated at the opening (78) of the cylinder (70), characterised in that the plastic housing (20) includes a thin-walled plastic cylinder (70) surrounding the valve (12) with the cylinder having an outer diameter sized to be received into the interior of the locking nut (64) of the male luer lock, and a tapered wedging member (72) extending about the plastic cylinder (70) with the wedging member having (i) a narrow end (74) adjacent the cylinder opening (78) sized to be received into the interior of the locking nut (64) of the male luer lock, and (ii) a wider end spaced from the cylinder opening (78) such that the wedging member (72) strengthens the cylinder (70) and interacts with the internal threads of the locking nut (64) of the male luer lock to lock the male luer lock (54) to the device with the valve (12) opened by the luer taper (52).

2. A medical device (10) for coupling to a standard male luer lock (54) having a luer taper (52) and an internally threaded locking nut (64) thereabout, the medical device including a normally-closed valve (12) openable under pressure of the taper (52) of the male luer lock (54) thereagainst and a plastic housing (20) surrounding the valve (12), the

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housing having an opening (78) sized to receive the luer taper (52) therethrough with a top surface (56) of the valve (12) situated at the opening (78), characterised in that the plastic housing (20) includes a tapered exterior surface which is (i) narrow adjacent the opening and sized to be received into the interior of the locking nut (64) of the male luer lock, and (ii) wider spaced from the valve opening (78) such that the tapered exterior surface wedgingly interacts with the interior of the locking nut (64) of the male luer lock (54) to hold the male luer lock to the device with the valve opened by the luer taper.

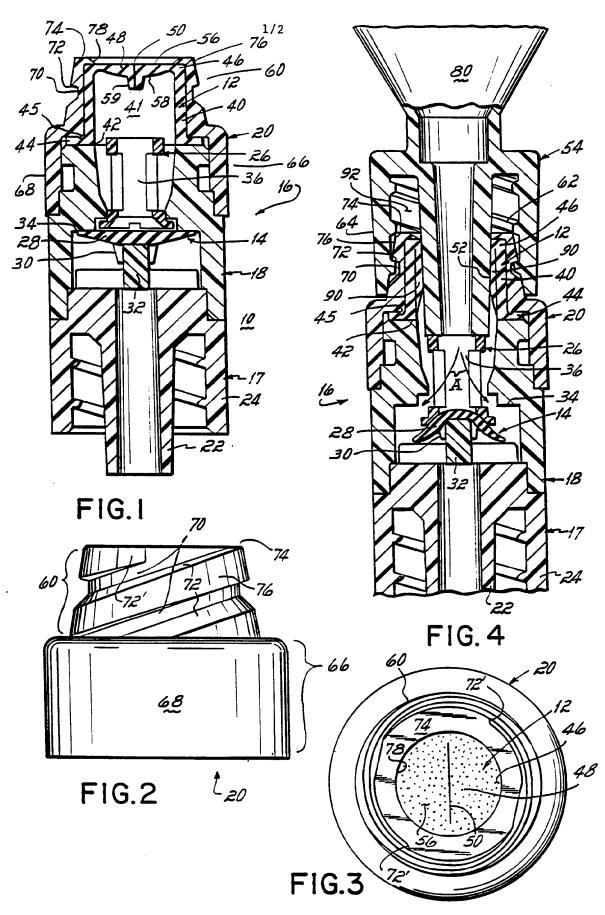
3. A medical device (10) for coupling to a standard male luer lock (54) having a luer taper (52) and an internally threaded locking nut (64) thereabout, the medical device including a normally-closed slit septum (48) valve (12) openable under pressure of the taper (52) of the male luer lock (54) thereagainst and a plastic housing (20) surrounding the valve (12), the housing having an opening (78) sized to receive the luer taper (52) therethrough with a top surface (56) of the valve (12) situated at the opening (78), and having a portion with an upper end adjacent the opening and a lower end spaced from the opening with a thread extending about the upper end, characterised in that the lower end of the housing portion is connected to the upper end of the housing portion by a tapered exterior surface which is (i) narrow adjacent the upper end and sized to be received into the interior of the locking nut (64) of the male luer lock, and (ii) wider adjacent the lower end such that the tapered exterior surface

- wedgingly interacts with the interior of the locking nut (64) of the male 15 luer lock to lock the male luer lock (54) to the device with the valve (12) opened by the luer taper inserted into the slit septum (48).
  - A medical device as claimed in claim 1 in which the 4. wedging member is a tapered plastic thread (72).
  - 5. A medical device as claimed in claim 4 further characterised by a second thread (72) extending about the plastic cylinder (70) and intertwined with the first-mentioned thread (72).
  - 6. A medical device as claimed in claim 5 wherein the second thread (72) is tapered with (i) a narrow end (74) adjacent the cylinder opening (78) sized to be received into the interior of the locking nut (64) of the male luer lock, and (ii) a wider end spaced from the cylinder opening (78) such that the first and second threads cooperate to strengthen the cylinder (70) and interact with the internal threads of the locking nut (64) of the male luer lock to lock the male luer lock (54) to the device with the valve (12) opened by the luer taper (52).
  - A medical device as claimed in claim 2 wherein the 7. housing further includes a thread (72) extending thereabout.

- 8. A medical device as claimed in either claim 3 or claim 7 further characterised in that a portion of the tapered exterior surface is defined by the thread (72).
- 9. A medical device as claimed in any one of claims 2, 3, 4, 5, 6, 7 and 8 wherein the thread (72) is truncated.
- 10. A medical device as claimed in claim 1 further characterised by a second wedging member (72) having (i) a narrow end (74) adjacent the cylinder opening (78) sized to be received into the interior of the locking nut (64) of the male luer lock, and (ii) a wider end spaced from the cylinder opening (78) such that the wedging members (72) strengthen the cylinder (70) and interact with the internal threads of the locking nut (64) of the male luer lock to lock the male luer lock (54) to the device with the valve (12) opened by the luer taper (52).
  - 11. A medical device as claimed in any one of claims 1, 4, 5, 6 or 10 wherein the cylinder (70) and wedging member (72) are integrally formed as a single piece.
  - 12. A medical device as claimed in any one of claims 2,3, 4, 5, 6, 7, 8 or 9 wherein the thread (72) is comprised of plastic.

- 13. A medical device as claimed in any one of claims 2, 3, 4, 5, 6, 7, 8, 9 or 12 wherein thread (72) has a major diameter and a minor diameter, and being further characterised in that at least one of the major and minor diameters is tapered so as to be narrow adjacent the cylinder opening (78) and wider spaced from the cylinder opening (78).
- 14. A medical device as claimed in claim 13 wherein only the major diameter is tapered.
- 15. A medical device as claimed in any preceding claim wherein the valve (12) includes an annular flange (44), and the medical device further includes a support member (18) cooperating with the housing (20) to grip the valve flange (44), the medical device further characterised by an annular ring (45) interposed between the flange (44) and one of the housing (20) and support member (18).
- 16. A medical device as claimed in claim 14, the ring (45) being formed as part of one of the housing (2) and support member (18).
- 17. A medical device as claimed in either claim 15 or claim 16 wherein the ring (45) is interposed between the housing (20) and the flange (44).

18. A medical device as claimed in any one of claims 15, 16 or 17 wherein the ring (45) is formed as part of the housing (20).



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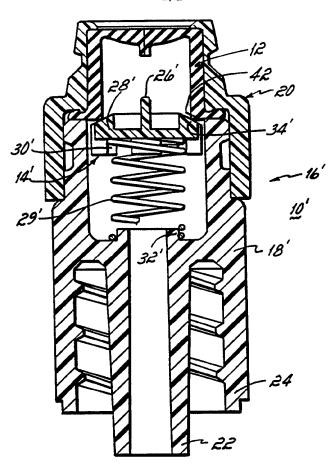


FIG.5

# INTERNATIONAL SEARCH REPORT

Int. donal Application No PCT/US 94/13757

A CLASSICICATION OF SUPERIOR	PC1/U3 94/13/3/
A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61M39/10 A61M39/04 F16L15/06	
According to International Patent Classification (IPC) or to both national classification	and IPC
B. FIELDS SEARCHED  Minimum documentation searched (classification system followed by classification sym	
IPC 6 A61M F16L	100IS)
Documentation searched other than minimum documentation to the extent that such do	cuments are included in the fields searched
Electronic data base consulted during the international search (name of data base and, w	where practical, search terms used)
C. DOCUMENTS CONSIDERED TO BE RELEVANT	
Category ° Citation of document, with indication, where appropriate, of the relevant p	passages Relevant to claim No.
US,A,5 251 873 (ATKINSON ET AL.) 12 October 1993 see column 5, line 54 - column 8, lin see column 9, line 61 - column 10, li see figures 1-3,12	2,7-10, 13,14 ine 16
4	1,3
US,A,4 244 607 (BLOSE) 13 January 198 see column 2, line 49 - column 3, lin see figures 1,2	31 ne 4
US,A,5 092 857 (FLEISCHHACKER) 3 Marc 1992 see column 4, line 48 - line 64 see figure 1	9,13,14
-/	
X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
A' document defining the general state of the art which is not considered to be of particular relevance investigated to be of particular relevance investigated to be of particular relevance.  E' earlier document but published on or after the international filing date  L'' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  O' document referring to an oral disclosure, use, exhibition or other means  P' document published prior to the international filing date but later than the priority date claimed  '&' document which may throw doubts on priority claim(s) or investigate or investigate of the priority date claimed  'X' document published prior to the international filing date but later than the priority date claimed	or document published after the international filing date priority date and not in conflict with the application but ed to understand the principle or theory underlying the vention nument of particular relevance; the claimed invention not be considered novel or cannot be considered to to tolve an inventive step when the document is taken alone nument of particular relevance; the claimed invention not be considered to involve an inventive step when the cument is combined with one or more other such documents, such combination being obvious to a person skilled the art.
Pate of the actual completion of the international search  6 April 1995	e of mailing of the international search report
ame and mailing address of the ISA  European Patent Office, P.B. 5818 Patentiaan 2	horized officer
NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Schönleben, J

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Int tional Application No
PCT/US 94/13757

(Continue	PCT/US 94/13757				
egory °	continuation) DOCUMENTS CONSIDERED TO BE RELEVANT  pory Citation of document, with indication, where appropriate, of the relevant passages    Relevant to claim No.				
	US,A,5 242 393 (BRIMHALL ET AL.) 7 September 1993 see column 2, line 28 - line 38 see figure 1	9,13,14			
	WO,A,91 09643 (MEDICAL INNOVATIONS CORP.) 11 July 1991 see figures 7,8	1,3,6			
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